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NEWSLETTER OF THE QUALITY ENHANCEMENT RESEARCH INITIATIVE—SUBSTANCE USE DISORDERS MODULE

the SAMpler

Department of Veterans Affairs

AUDIT-C: AN EFFECTIVE BRIEF METHOD FOR PRIMARY CARE ALCOHOL SCREENING

Katharine Bradley, M.D., M.P.H.

Primary care interventions as brief as 5 minutes can improve health outcomes for patients with hazardous drinking and those with milder problem drinking. Hazardous drinking refers to drinking above recommended levels, whereas problem drinking refers to drinking that has already resulted in adverse psychosocial, legal, economic or medical problems. Among patients with hazardous or mild problem drinking, brief interventions can decrease alcohol consumption, blood pressure, serum liver enzymes, and health care utilization. Primary care providers can also help motivate patients with severe alcohol dependence to accept appropriate specialty referral. Many more primary care patients have hazardous or mild problem drinking than have alcohol dependence. Therefore primary care alcohol screening questionnaires need to identify both patients with hazardous drinking and milder alcohol problems, as well as those with alcohol dependence.

Based on the efficacy of brief interventions, the VA began requiring annual primary care alcohol screening in 1997. A recent QUERI-SAM survey of alcohol screening practices in VA primary care clinics by Barry and colleagues found that clinics relied almost exclusively on the CAGE questionnaire. The CAGE is a 4-item questionnaire that has been used for iden

AUDIT-C *continued page 6*

AUDIT-C: each question is worth up to 4 points for a total possible score of 0-12.

1. How often have you had a drink containing alcohol in the past year? Consider a drink to be a bottle of beer, a glass of wine, a wine cooler, or one cocktail or a shot of hard liquor (like scotch, gin or vodka).

- ☐ **Never** (0 points)
- ☐ **Monthly or less** (1 point)
- ☐ **2-4 times/month** (2 points)
- ☐ **2-3 times/week** (3 points)
- ☐ **4-5 times/week** (4 points)
- ☐ **6 + days/week** (4 points)

2. How many drinks did you have on a typical day when you were drinking in the past year?

- ☐ **0 drinks** (0 points)
- ☐ **1-2 drinks** (0points)
- ☐ **3-4 drinks** (1 point)
- ☐ **5-6 drinks** (2 points)
- ☐ **7-9 drinks** (3 points)
- ☐ **10 + drinks** (4 points)

3. How often did you have 6 or more drinks ("4 or more drinks" = modification for women) **on one occasion in the past year?**

- ☐ **Never** (0 points)
- ☐ **Less than monthly** (1 pt)
- ☐ **Monthly** (2 points)
- ☐ **Weekly** (3 points)
- ☐ **Daily or almost daily** (4 points)

Scoring: A score of ≥4 identifies 86% of men who report drinking above recommended levels or meet diagnostic criteria for alcohol use disorders. A score ≥ 2 identifies 84% of women who report hazardous drinking or alcohol use disorders.

Task Force Review of VA Naltrexone Policy

Committee Members: *Joyce Cramer, BS; Daniel Kivlahan, PhD; John Krystal, MD; Philip Lavori, PhD; Charles O'Brien, MD, PhD; Robert Roseneck, MD; Bruce Rounsaville, MD; (Chair), Mark Willenbring, MD*

This task force was convened to consider the implications for VA policy on the treatment of alcoholism of the recently published study by Krystal et al in the New England Journal of Medicine from VA Cooperative Study 425 (CSP 425). The study was a randomized clinical trial of 627 VA patients at 15 VA medical centers. Experimental patients received naltrexone for up to one year and all patients received 12-step facilitation therapy. The study found no statistically significant benefit for naltrexone in preventing short-term relapse, reducing the intensity of drinking once relapse had occurred, or on the proportion of days in which drinking occurred up to 52 weeks.

VA research service is to be commended for having conducted this landmark study which substantially adds to our understanding of the efficacy of naltrexone. Although this is the largest study of naltrexone yet completed, it needs to be understood in the context of the extensive VA and non-VA-based research literature on naltrexone. This research literature has been reviewed in several recent analyses, which concluded that naltrexone is effective in the treatment of alcohol dependence but that the magnitude of its effect is small.

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OPIATE INITIATIVE NOW IMPLEMENTED IN 9 CLINICS

Hildi Hagedorn, PhD

The OpiATE Initiative is a multi-site demonstration project whose goal is to examine the feasibility and effectiveness of implementing four evidence-based practices in opioid agonist therapy (OAT) for opioid dependence. OpiATE Initiative staff have developed a toolkit to assist clinic staff in implementing these practices. The OpiATE Monitoring System (OMS) is a quick and simple method to document current and ongoing clinic practice relevant to the four target practices of adequate dose, adequate counseling frequency, focusing on maintenance and retention of patients, and systematic use of contingency management techniques. The OMS provides systematic feedback to individual clinics by clinic and staff member, and allows comparison of a specific clinic's practices with others. A facilitated quality improvement process is used to assist clinics to examine their data, set goals for change, and determine how successful they are in achieving them.

The project has recruited nine VA OAT clinics. Four clinics are currently involved in the facilitated quality improvement intervention and two are currently submitting baseline data only. The remaining three clinics are expected to be collecting data shortly. This update presents a summary of the baseline clinic data and qualitative information regarding implementation of the intervention, based on OMS and site visit data.

Target 1: Adequate Dose: Adequate dose is defined as 60 mg or greater of methadone or its equivalent, or appropriate use of a lower dose as determined based on a clinical decision algorithm. The number of clients in each clinic receiving the recommended methadone dose of 60mg or greater ranged from 43% to 78% (Figure 1). Dose reviews completed with three of the intervention clinics have confirmed that a significant minority of

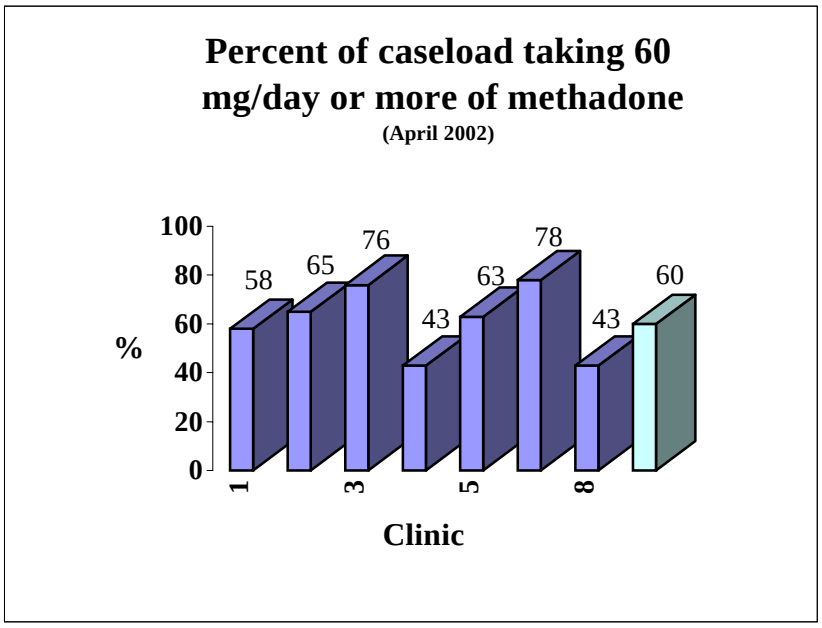

figure 1

clients, perhaps up to 25%, are successfully maintained for years at doses below 60mg. Nevertheless, there is considerable variation across sites in dosing approaches. Intervention has focused on identifying clients with low doses that continue to struggle with illicit opiate use as well as promoting change in dosing strategies for new clients. Clinics are being encouraged to increase new clients' doses to 60mg and to provide increases beyond 60mg for clients that continue to struggle with illicit opiate use rather than using punitive consequences such as dose decreases or administrative discharge.

Target 2: Counseling Frequency: The mean number of counseling visits per month ranged from 1.2 to 3.9. All clinics are currently meeting the minimum standard of one visit per week in the first month of treatment and one visit per month after that.

Target 3: Maintenance Orientation: Available evidence provides strong support for focusing on retention and long-term maintenance of patients in OAT. Initially, clinic staff were asked to report whether each client's goal was maintenance or detoxification, and all clinics reported that greater than 90% of clients currently had a maintenance goal. However, clinic policies regarding responses to continued drug use, which other drugs were considered "positive" (e.g., cannabis), and administrative discharge varied considerably, based on site visits and policy reviews. These more general attitudes and policies are captured by the Abstinence Orientation Scale (Caplehorn, JRM, et al., 1998). Mean clinic scores on the Abstinence Orientation Scale ranged from 2.0 to 3.1 (Figure 2). Scores of greater than 3.0 are considered to be supportive of an abstinence orientation. Abstinence Orientation Scale scores were strongly negatively correlated with percentage of clients receiving doses of 60mg or greater (-.79). Higher Abstinence Orientation Scale scores were also indicative of more punitive approaches to continued illicit drug use. Intervention in this area has focused on education regarding the extremely poor outcomes of clients who are discharged from OAT, encouragement of reinforcement of positive behaviors rather than relying on punitive measures, and discouragement of administrative discharge.

Target 4: Contingency Management (CM): Systematic use of reinforcers has been shown in multiple randomized trials to improve outcomes.

Opiates *continued next page*

Opiates *from previous page*

Although all clinics have contingencies such as revocation of take-home privileges, none of the clinics are using the reinforcing power of take-home incentives in the most productive way. Generally, clinics are requiring complete abstinence from all substances for 90 days before an additional take-home is awarded and clients are responsible for requesting take-home privileges. We are promoting a CM protocol in which the case manager awards a take-home privilege for a much smaller behavioral goal (e.g., one urine sample negative for illicit opiates). This allows new clients, generally those struggling the most, to receive some recognition for small steps toward decreasing illicit opiate use. We have developed a package of materials to assist clinics in evaluating their current take-home policies and identifying potential changes.

The baseline and qualitative intervention data confirm our expectations that clinics vary greatly in their baseline implementation of best-practice guidelines and that individualization of the intervention to each clinic is essential. However, even clinics with excellent overall practices have found they were not using available evidence fully, especially regarding contingency management. Overall, the OMS is working very well, and as has been well-accepted by clinics.

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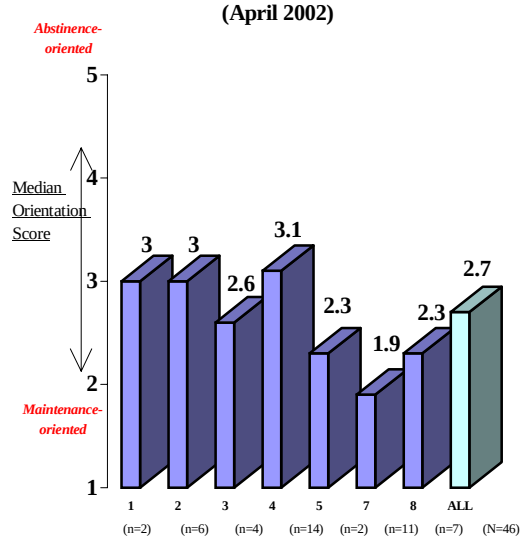

Figure 2

EDITOR'S COLUMN

Results of Coop Study 425 Illustrate Perils of "Evidence-Based Medicine"

Mark Willenbring, MD, QSAM National Clinical Coordinator

I recently had the privilege of participating in a group charged with advising senior VA leadership on the policy implications of VA Coop Study 425 (see statement in this issue of the SAMpler). This study was a large, multi-site, placebo-controlled, randomized controlled trial (RCT) of oral naltrexone for the treatment of alcohol dependence. The results were about as negative as is possible in such a trial. Naltrexone showed no benefit over placebo in short term (3 month) or long-term outcomes (12 month). This was in contrast to multiple previous RCTs that showed a significant effect on reducing relapse.

The Executive Committee for the QUERI Substance Abuse Module (QSAM) had discussed naltrexone several times at previous meetings, because the quality of evidence for its efficacy is relatively high compared to other intervention in addiction treatment (except perhaps methadone maintenance). However, naltrexone use in the VA was relatively minimal, so we were discussing whether to recommend a major push to implement it more widely. In our recent survey (see <http://www.chce.research.med.va.gov/chce/pdfs/qsampsfr.pdf>) program leaders had reported that it was used in only 1-25% of patients, and 26% of sites reported that it was not even available for use. The QSAM Executive Committee was aware, however, that the Coop study was in process, and elected to await its results before making a decision.

That turned out to be a good judgment, given the eventual results of the VA study. VA patients are older, had been drinking longer, and fewer were employed or married compared with previous studies. In addition, naltrexone may work better with cognitive behavioral therapy than it does with twelve-step facilitation. Future studies will no doubt attempt to sort these factors out.

However, in addition to the specific implications for using naltrexone, this is an example of the potential pitfalls of applying current evidence to practice. There is a danger of reifying the randomized controlled trial at the expense of much-maligned clinical (anecdotal) experience. Clinical patients are usually different from study patients, yet we have to rely on published results to guide us. In addition, it seems that no matter how carefully studies are designed and carried out, each has methodological shortcomings that call the results into question. What seems like truth one day is false the next. Mammography is a prominent example, and there are many others. In the end, a patient needs a clinician to sort all of this out and to arrive at the best course of action. The Task Force examined the actual practice in the VA, and found that about 1% of patients with a diagnosis of alcohol dependence had received a prescription for naltrexone in FY 2000. That is, clinicians were using it quite selectively, having learned through clinical experience that naltrexone was not all that effective in our real-life patients. In the end, we decided that, guess what? The clinicians had it about right after all.

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Intervention Phase of Smoking Cessation Project to Begin

Annamay Snyder, B.A.

An article in the last issue of the SAMpler introduced a newly funded VA Health Services Research and Development Service project entitled "Facilitating Implementation of the PHS Smoking Cessation Guideline". The project, led by Melissa Partin, Ph.D. and Anne Joseph, M.D, M.P.H. from the Center for Chronic Disease Outcomes Research at the Minneapolis VA Medical Center, will be evaluating strategies for linking smokers interested in quitting with appropriate treatments. Since the project began in October, 2001, eight VA Medical Centers (Seattle, Providence, Birmingham, New Orleans, Salt Lake City, Houston, Jackson, and Denver) have agreed to participate and each site has brought together primary care providers, pharmacists, and smoking cessation clinic representatives to review and provide input on intervention strategies.

The input received suggests that VA facilities vary considerably on key organizational factors such as: how integrated smoking cessation counseling services are with primary care; who can prescribe pharmacological treatments for smoking cessation; and what restrictions are placed on these prescriptions. Hence, a challenge for the project team has been to develop strategies that are flexible enough to be effectively applied in all of these settings. Originally, only patients and their primary care providers would be involved in the intervention (through a patient letter and/or call, and generic versus tailored provider prompts). To increase the potential for the interventions to be effective at sites where primary care providers cannot prescribe smoking cessation therapy, the revised intervention materials will not only be delivered to patients and primary care providers, but also to one additional appropriate clinician (such as a smoking cessation clinic facilitator).

The intervention phase of this project will begin in May of this year.

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Naltrexone *from page 1*

Although the recent VA study showed no benefit of naltrexone therapy, other well conducted studies have shown positive benefits for naltrexone and it is notable that in several of these studies cognitive behavioral therapy was used instead of the 12-step facilitation used in CSP 425. Thus, it is possible that while naltrexone does not seem to be effective when delivered with 12-step facilitation therapy, future studies may show it to be effective in the context of other psychosocial treatments. In addition, it is possible, in view of the past positive studies, that naltrexone will be found to be effective in selected clinical subgroups, at higher dose or in combination with other medications. Several studies are currently underway both within the VA and outside the VA to clarify the value of naltrexone in these contexts.

While the VA data from CSP 425 do not support the continued prescription of naltrexone for alcoholism, the presence of other supportive data justifies continued, but limited naltrexone use. In fact, an analysis of merged data from VA's patient encounter file and from the pharmacy benefits management system conducted as part of this review showed that only one per cent of patients given a diagnosis of alcohol abuse or dependence in fiscal year 2001 received any naltrexone therapy during the fiscal year. The results of CSP 425 suggests that there is no evidence to support a national naltrexone policy that would broaden naltrexone prescription beyond current practice of limited use. Nonetheless, the overall positive literature on naltrexone would argue against removing naltrexone from the VA formulary or making it a non-formulary drug.

In view of this important study and other recent advances in the field of alcohol treatment, VA should support educational programs that would bring clinical staff up-to-date on recent major research studies in the treatment of alcoholism.

One of the striking findings of this study is that outcomes in all treatment groups were very good with drinking on less than 11%-14% of potential drinking days during the first 13 weeks of the trial and only 15%-19% days over the entire year. These results represent a reduction of drinking by over 80% in all treatment conditions. Although naltrexone was not associated with increased treatment efficacy, this study shows that well-staffed multidisciplinary specialized treatment programs can be quite effective in the treatment of this severe illness. These positive findings give support to current efforts to restore VA's capacity to provide specialized services for addictive disorders.

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VHA/DOD CLINICAL PRACTICE GUIDELINE RECEIVES FULL APPROVAL

Dan Kivlahan, PhD

The VHA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders (SUD's) in Primary and Specialty Care Settings (Version 1.0) has now received full VHA approval. The full guideline is posted on the Office of Quality and Performance (OQP) website http://www.oqp.med.va.gov/cpg/cpg.htm using a hypertext format that links annotation and evidence tables with specific steps in the clinical algorithm. The website also provides printable versions of provider tools (pocket cards, key points and summaries). Laminated versions of these tools have been distributed to each facility and additional copies are available using an **Order Pocket Cards/ Tools** button on the main SUD guideline web page.

Effective guideline implementation has been conceptualized as relying on 4 A's: awareness, agreement, adaptation (to local circumstances), and finally adherence. Several parallel efforts are addressing these steps.

To promote awareness of the guideline, the VA Employee Education System is developing an independent study course using the SUD satellite broadcast originally aired last October. The study package will include the 2-hour videotape of the broadcast, 20 test questions, instructions for continuing education credit (for MDs, RNs, psychologists, and pharmacists) and reference materials, (i.e. bibliographies, web addresses). The program package will be sent to education contacts and libraries at each medical center later this spring.

In another guideline awareness initiative, Ken Weingardt and colleagues at the PERC in Palo Alto have begun a project to develop and evaluate a web-based approach to training providers on modules of the guideline, beginning with the Stabilization Module. Pilot testing will begin this spring and will be announced via Outlook and the mental health intranet site.

As indicated in the QUERI survey of treatment program leaders (http://vaww.mentalhealth.med.va.gov/substance_use.htm), some respondents did not agree that there was adequate research evidence to support some of the recommended practices.

Comments or questions about the guideline are welcome and encouraged, but few have been received. The main SUD guideline web page now has a convenient **Contact/ Feedback** feature that we encourage you to use.

Within VHA, Performance Measures are among the most influential mechanisms for promoting and monitoring guideline adherence. The Draft 2002 Network Director Performance Plan originally included a measure mandating that at least one staff member in each specialized Substance Abuse Program receive training in Cognitive Behavior Therapy and Motivational Interviewing. Concerns about the measure included the apparent inconsistency with the evidence as presented in the guideline (underemphasizing the importance of 12-step facilitation and other evidence based interventions), ambiguity in technical parameters of the measure (e.g., identifying acceptable training), recent empirical findings documenting ineffectiveness of similar approaches to technology transfer in addiction treatment, and prospects for developing and providing more efficient and accessible training. Through an active dialog with the OQP, the proposed measure was removed for FY02 and an alternative measure proposed for FY03 that emphasizes continuity of care and treatment retention in specialty care. We will provide more details about that guideline adherence measure in the next SAMpler.

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tifying alcohol use disorders since the 1960s and is widely taught in medical schools.

However, whereas the CAGE screens for lifetime alcohol use disorders—alcohol abuse or dependence — it was not designed to identify more recent hazardous drinking. The addition of 3 questions about alcohol consumption can improve the CAGE's performance as a screening test for hazardous drinking, but lengthens the questionnaire beyond what is practical in most VA primary care clinics.

The QUERI-SAM Executive Committee recently reviewed the literature on primary care alcohol screening, including recent VA research funded by HSR&D. This review concluded that a 3-item questionnaire, the AUDIT-C (See Box), was at least as effective as the CAGE in VA populations, and appeared to have important advantages.

Key findings of the review included:

- The CAGE is not an effective screening test for hazardous drinking, as it identifies only 49% of male VA patients who drink above recommended levels. Moreover, the CAGE only identifies 77% of male primary care patients who meet diagnostic criteria for alcohol use disorders when a score of 2 or more, the usual cut-point, is considered a positive screen. Half of VA patients who screen positive on the CAGE no longer drink alcohol. The CAGE is less effective in women than men, and has been especially weak in studies of white women, but is not well studied in female VA patients.
- The AUDIT-C provides excellent screening for hazardous drinking in VA primary care patients, as expected, since it asks directly about alcohol consumption. However, these 3-items also screen effectively for alcohol use disorders in VA patients. An AUDIT-C score $\geq$ 4 identifies 86% of men who report drinking above recommended levels or meet diagnostic criteria for alcohol use disorders, whereas a score $\geq$ 2 on a gender-modified AUDIT-C identifies 84% of women who report hazardous drinking or alcohol use disorders.

VA patients who screen $\geq$ 8 on the AUDIT-C are more likely to die over 4-5 years follow-up compared to those with lower AUDIT-C scores, even after taking into account age, smoking and other factors known to affect survival. In contrast, the CAGE ($\geq$ 2) was not a significant predictor of mortality when other factors affecting survival were taken into account, even after exclusion of non-drinkers.

- The AUDIT-C has been used at VA Puget Sound for the past few years. Nurses have reported that the 3 AUDIT-C questions are easier and more comfortable to ask than the CAGE questions. Primary care providers have readily accepted the AUDIT-C. Because the AUDIT-C identifies hazardous drinking as well as active alcohol use disorders, more patients screen positive when it is used for primary care screening (19%), than when the CAGE questionnaire is used (9%).
- The third question of the AUDIT-C performs better as a single-item screening question than the CAGE for identification of hazardous drinking and/or active alcohol use disorders.
- Another major priority of the QUERI-SAM is to increase the use of effective brief interventions in primary care clinics in the VA. While trials have shown brief interventions work in research settings, little is known about how to increase effective use of brief interventions in the "real world" without additional research-supported personnel. Using the VA Computerized Patient Record System (CPRS), a clinical reminder about alcohol counseling is being developed for primary care providers. When a patient screens positive on the AUDIT-C administered by nurses, a CPRS clinical reminder will be activated for the primary care provider. The reminders will help providers assess and document the severity of hazardous or dependent drinking as well as patients' readiness to change and plans for management or referral. The reminder will initially be evaluated and refined at VA Puget Sound, in a two-year trial funded by the RWJ Foundation. If it is effective, it will be evaluated in a multi-site VA trial and will become available for dissemination to other VA sites.

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In our next issue:

the SAMpler will change its name!

The new name will be:

"SUDden IMPACT"